APR 11 2002

K020099

510(k) Summary
Ceralas Diode Laser System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

biolitec, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028
Phone: (413) 525-0600
Facsimile: (413) 525-0611
Contact Person: Carol J. Morello, V.M.D.

Date prepared: January 9,2002

Name of Device and Name/Address of Sponsor

Mega Beam/Ceralas Nonsterile Collimating Handpiece
biolitec, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028

Classification Name

Accessory to Surgical Laser Instrument

Predicate Device

biolitec Inc. Mega Beam/Ceralas Nonsterile Collimating Handpiece

Intended Use/Indications for Use

The biolitec, Inc. Mega Beam/Ceralas Nonsterile Collimating Handpiece is intended to be used as a fiberoptic laser delivery accessory with the CeralasD 980nm Diode Laser for the dental indications that the laser has already been cleared for in K983058, K991891 and K993002. Please refer to the Laser User Manual for the specific list of indications.

Technological Characteristics

The Mega Beam/Ceralas Collimating Handpiece consists of a 3 meter quartz optical fiber encased in a handpiece. The handpiece has lenses that collimate the beam to create a 7mm beam and resulting 7mm spot size.

Performance Data

biolitec conducted testing comparing the Mega Beam Ceralas Collimating Handpiece's and the Mega Beam Bare Fiber's handpiece efficiency, energy density and divergent half angle. These performance tests demonstrate that the Mega Beam/Ceralas Collimating Handpiece is as safe and effective as the bare fiber optic delivery system.

Substantial Equivalencies

The Mega Beam/Ceralas Collimating Handpiece has the same intended use as its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 11 2002

Ms. Carol J. Morello, VMD
Regulatory Affairs
Biolitec, Inc.
515 Shaker Road
East Longmeadow, MA 01028

Re: K020099
Trade/Device Name: Mega Beam/Ceralas Nonsterile Collimating Handpiece
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology
Regulatory Class: II
Product Code: GEX
Dated: January 9, 2002
Received: January 11, 2002

Dear Dr. Morello:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

for Mark N Milhous

Celia M. Witten, Ph.D., M.D.
Directir
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K 020099

Device Name: Mega Beam/Ceralas Nonsterile Collimating Handpiece

Indications for Use:

The biolitec, Inc. Mega Beam/Ceralas Nonsterile Collimating Handpiece is intended to be used as a fiberoptic laser delivery accessory with the CeralasD 980nm Diode Laser for the dental indications that the laser has already been cleared for in K983058, K991891 and K993002. Please refer to the Laser User Manual for the specific list of indications.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use___
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)

for Mark N Milhern
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020099

\\\DC - 61213/1 - #1331532 v1